

REMARKS

Claims 2-5 and 7, and 9-34 are pending in the application. Claims 9, 16, 17, and 26 are independent claims.

Claims 4-5, 9-14, 16-18, 21-22, 24-26, 27, 30-31, and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,843,691 to Douglas et al.

Before discussing the specifics of the rejection, the Examiner statement on page 2 lines 15-16 of the Final Office Action that "Applicant's state Douglas et al. does not teach a reagent-impregnated membrane" is respectfully traversed. The Examiner's attention is directed to page 7, last paragraph of the Reply filed on November 16, 2004, where it is recited that "Douglas discloses a reagent test strip that has a porous matrix that incorporates a testing reagent that undergoes a color change in response to the analyte in a biological fluid sample that is applied to the strip". As such, the undersigned wishes to clarify that no misleading statement regarding the scope of the cited art was made.

It is proposed that claims 9, 16, 17, and 26 each be amended to clarify that the carrier has a carrier surface defined by opposite carrier ends and that the border is positioned at one of the carrier ends, such that the detection element is downstream of the cover. Support for the amendments is found in the specification and figures and particularly figures 1-1G. The amendments are properly entered here since they do not raise any issues requiring additional search and they either put the claims in condition for allowance or at least in a better form for appeal. Entry of the proposed amendments is requested.

It is submitted that Douglas fails to disclose or suggest the device as recited by amended claims 9, 16, 17, and 26 for at least the reasons set forth below.

In light of the amendments to claims 9, 16, 17, and 26, the layers (22, 20) of Douglas et al. fail to meet the claimed requirements of having first and second edges of the cover. As discussed above, it is proposed that the independent claims be amended to recite that the channel has a sample application opening defined by at least one border positioned at one of the carrier ends, the channel extending at least from the opening

to the second end of the detection element, such that the detection element is downstream of the cover.

The Examiner's attention is directed to Column 12 lines 47-51 as well as Figure 2 of Douglas et al. where it is taught that the "sample is introduced through sample hole 30 and is directed by capillary action along central channel 32 of intermediate layer 24 to each of the assay area and the timing area, any excess sample being absorbed in absorbent layers 20 and 22". In contrast to the amended claims, the sample hole (30) shown in Figure 2 is spaced apart from an end of the bottom layer (26). Further, in direct contrast to the claimed invention, the layers (22, 20) are downstream of the matrix (10).

Douglas fails to disclose or suggest a device comprising "a carrier having a carrier surface defined by opposite carrier ends, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and first and second opposite edges, the second edge facing the first end of the detection element, the cover cooperating with the carrier surface and with the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends, the channel extending at least from the opening to the second end of the detection element, such that the detection element is downstream of the cover and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 9.

Further, there is no disclosure or suggestion in Douglas of a method for withdrawing a liquid sample into an analytical element, the method comprising the steps of "providing a device that comprises a carrier having a carrier surface defined by opposite carrier ends, a detection element having opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the detection element, the cover cooperating with a the carrier surface and the detection element to form a capillary-active channel having a sample

application opening defined by at least one border positioned at one of the carrier ends, the channel extending at least from the opening to the second end of the detection element such that the detection element is downstream of the cover, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface opposite to the at least one notch facing the channel is exposed and contacting the border of the sample application opening adjacent to the notch with the liquid sample so that the liquid sample is transported by capillary forces into the channel", as recited by amended claim 16.

Still further, Douglas does not disclose or suggest a device comprising "a carrier having a carrier surface defined by opposite carrier ends, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface facing the carrier and opposite first and second edges, the second edge facing the first end of the detection element, and the cover cooperating with a the carrier surface and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends and extending at least from the opening to the second end of the membrane, such that the detection element is downstream of the cover, and wherein at least one notch in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 17.

Still further, there is no description or suggestion in Douglas of a device comprising "a carrier having a carrier surface defined by opposite carrier ends, and a cover having a surface that faces the carrier and that cooperates with the carrier surface to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends and wherein at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one border of the sample application

opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 26.

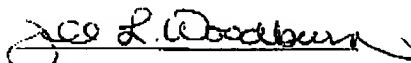
As such, claims 9, 16, 17, and 26 as amended are not anticipated and are believed to be patentable over Douglas. Claims 4, 5, and 10-14 depend from amended claim 9. Claims 18, 21, 22, and 24 depend from amended claim 17. Claims 27-34 depend from claim 26.

It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 102(b). Entry of the amendments leading to reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

This application is deemed to be in condition for allowance and as such is respectfully requested. In addition, if necessary, it is requested that this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and fees be charged to Deposit Account No. 50-0877 (with reference to RDID 0043 US).

Respectfully submitted,

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